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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/023,970	12/13/2001	Marcus B. Gohlke	069349.0120	4120

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[REDACTED] EXAMINER

COE, SUSAN D

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1651

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/021,970	GOHLKE, MARCUS B.
Examiner	Art Unit
Susan Coe	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
4a) Of the above claim(s) 19-24 is/are withdrawn from consideration.
5) Claim(s) ____ is/are allowed.
6) Claim(s) 1-18 is/are rejected.
7) Claim(s) ____ is/are objected to.
8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1 Certified copies of the priority documents have been received.
 2 Certified copies of the priority documents have been received in Application No. _____.
 3 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draft Patent Drawing Review (PTO-894)
3) Response to Appeal Brief
4) Other: _____

- 4) Interview Summary (PTO-413) Paper No(s) _____
5) Notice of Informal Patent Application (PTO-150)

DETAILED ACTION

1. Claims 1-24 are currently pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-18, drawn to a beta glucan and lactoferrin composition, classified in class 424, subclass 535.
 - II. Claim 19, drawn to a method of treating cancer, classified in class 424, subclass 535.
 - III. Claim 20, drawn to a method of treating bacterial infection, classified in class 424, subclass 535.
 - IV. Claim 21, drawn to a method of treating fungal infection, classified in class 424, subclass 535.
 - V. Claim 22, drawn to a method of treating viral infection, classified in class 424, subclass 535.
 - VI. Claims 23 and 24, drawn to a method of treating septicemia, classified in class 424, subclass 535.

The inventions are distinct, each from the other because of the following reasons:

3. Invention I is related to Inventions II-VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

§ 806.05(h)). In the instant case the product can be used in a different process, such as the use of beta-glucan as a source of dietary fiber.

4. Inventions II-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Each of the inventions is drawn to treating a different disease state. This shows that each invention has a different function.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. William Beard on February 5, 2002 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18. Affirmation of this election must be made by applicant in replying to this Office action.

5. Claims 19-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Claims 1-18 are examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

7. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,296,464, US Pat. No. 5,783,569, and US Pat. No. 5,670,138.

US '464 teaches using lactoferrin to treat bacterial infections (see claims). The lactoferrin can be derived from cow's milk (see column 3, lines 22-32). The isolated lactoferrin can be administered in food or with other known carriers (see column 3, lines 56-59). The administration of the lactoferrin in food would require chewing on the part of the recipient. The chewing would help dissolve the active ingredients into the oral cavity.

US '569 teaches using beta glucan derived from yeast to treat bacterial infection (see claims 17-22). The beta-glucan can be administered in the form of a tablet (see claim 84). US '569 does not specifically teach that the beta-glucan can be derived from mushrooms or oats; however, these two sources of beta-glucan are well known in the art. A person of ordinary skill in the art would expect that beta-glucan from these sources would be able to function in the manner taught by US '569.

These references show that it was well known in the art at the time of the invention to use beta glucan and lactoferrin in antibacterial compositions. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-

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Based on the disclosure by the references that these substances are used in antibacterial compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating antibacterial compositions. Therefore, the artisan would have been motivated to combine beta glucan and lactoferrin into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

US '569 and US '464 also do not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on the knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

US '569 and US '464 also do not specifically teach combining beta-glucan and lactoferrin with lemon flavoring, mannitol, sorbitol, and silicon dioxide. However, US '138 teaches that these ingredients are used to formulate orally administered products (see column 6, lines 15 and 40-42). Therefore, an artisan of ordinary skill in the art would be motivated to use lemon flavoring, mannitol, sorbitol, and silicon dioxide in combination with the beta-glucan and

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The references teach combining the ingredients together; however, they do not specifically teach combining the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC

February 6, 2002

